JUN 1 0 2002

# 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: K014069

1. Date of Summary: Nov.30, 2001

2. Submitted by: Princeton BioMeditech Corporation
   4242 U.S. Route 1, Monmouth Jct., NJ 08852
   PHONE 732-274-1000
   FAX 732-274-1010
   Contact Person: Jemo Kang

3. Device Name: Trade Name: LifeSign®Home Drug Test (COC)
   Common or Usual Name: Immunoassay for detection of cocaine in human urine
   Classification Name: Drugs of Abuse Analysis Systems, Toxicology (91DIO for Enzyme Immunoassay)

4. Identification of legally marketed device to which claims equivalence: k990786; StatusDS™DOA10(MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP)

5. Device Description: LifeSign®Home Drug Test (COC) is simple one step immunochromatographic test for the rapid, qualitative detection of cocaine.

6. Intended Use: LifeSign®Home Drug Test (COC) is designed for the qualitative detection of cocaine metabolite, benzoylecgonine, at the cutoff of 300 ng/mL in human urine to assist in screening of drugs of abuse samples at home.

7. Substantial Equivalence: LifeSign®Home Drug Test (COC) is substantially equivalent to k990786; Status DS™DOA10. Both products use the same assay principle and immunochromatographic assay to detect cocaine metabolite qualitatively. The detection cutoff level is the same. The tests demonstrated 100 % correlation when 100 specimens (50 negative and 50 positive) were compared. The differences are that LifeSign®Home Drug Test (COC) detects cocaine use only, while StatusDS™DOA10 detects nine other drugs of abuse in addition to COC, and different antibody is used for cocaine detection.

8. Consumer Study: In a consumer study, LifeSign® Home Drug Test (COC) showed over 96% overall accuracy.

**Conclusion**: The device is substantially equivalent to the legally marketed device k990786, Status DS™DOA10 (MET/OPI/COC/THC/PCP/BZO/ BAR/MTD/TCA/AMP).

# 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: k014067

1. Date of Summary: Nov.30, 2001

2. Submitted by: Princeton BioMeditech Corperation
   4242 U.S. Route 1, Monmouth Jct., NJ 08852
   PHONE 732-274-1000
   FAX 732-274-1010
   Contact Person: Jemo Kang

3. Device Name: Trade Names: Stick Device: Status Stik™ COC, AccuSign® Stik COC, AccuStik™ COC
   Card Device: AccuSign® COC, Status DS™ COC
   Strip Test: AccuStrip™ COC
   Common or Usual Name: Immunoassay for detection of cocaine in human urine
   Classification Name: Drugs of Abuse Analysis Systems, Toxicology (91DIO for Enzyme Immunoassay)

4. Identification of legally marketed device to which claims equivalence: k990786; StatusDS™DOA10(MET/OPI/COC/THC/PCP/BZO/BAR/MTD/TCA/AMP)

5. Device Description: Status Stik™ COC is simple one step immunochromatographic test for the rapid, qualitative detection of cocaine.

6. Intended Use: Status Stik™ COC is designed for the qualitative detection of cocaine metabolite, benzoylecgonine, at the cutoff of 300 ng/mL in human urine to assist in screening of drugs of abuse samples. For *In vitro* Diagnostic Use.

7. Substantial Equivalence: Status Stik™ COC is substantially equivalent to k990786; Status DS™DOA10. Both products use the same assay principle and immunochromatographic assay to detect cocaine metabolite qualitatively. The detection cutoff level is the same. The tests demonstrated 100 % correlation when 100 specimens (50 negative and 50 positive) were compared. The differences are that Status Stik™ COC detects cocaine use only, while StatusDS™DOA10 detects nine other drugs of abuse in addition to COC, and different antibody is used for cocaine detection.

**Conclusion**: The device is substantially equivalent to the legally marketed device k990786, Status DS™DOA10 (MET/OPI/COC/THC/PCP/BZO/ BAR/MTD/TCA/AMP).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Jemo Kang, Ph.D.
Director
Princeton BioMeditech Corporation
4242 U.S. Route 1
Monmouth Junction, NJ 08852-1905

JUN 1 0 2002

Re: k014069
Trade/Device Name: LifeSign®Home Drug Test (COC)
Status Stik™ COC, AccuSign®Stik COC, AccuStik™ COC,
AccuSign® COC, Status DS™ COC, Strip: AccuStrip™ COC
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and cocaine metabolite test system
Regulatory Class: Class II
Product Code: DIO
Dated: April 9, 2002
Received: April 10, 2002

Dear Dr. Kang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K014067

Device Name: Stick: Status Stik™ COC, AccuSign®Stik COC, AccuStik™ COC
Card: AccuSign® COC, Status DS™ COC
Strip: AccuStrip™ COC

Indications For Use:

Immunoassay for the qualitative detection of cocaine metabolite, benzoylecgonine, at the cut-off of 300 ng/mL in urine to assist in screening of drugs of abuse samples. For *In vitro* Diagnostic Use

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K014069

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Professional Use:____

Prescription Use: X OR Over The Counter Use: ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

510(k) Number (if known): K014067

Device Name: LifeSign®Home Drug Test (COC)

Indications For Use:

Immunoassay for the qualitative detection of cocaine metabolite, benzoylecgonine, at the cut-off of 300 ng/mL in urine to assist in screening of drugs of abuse at home. For *In vitro* Diagnostic Use

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K014067

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Professional Use:_____

Prescription Use:_____ OR Over The Counter Use: X

(Per 21 CFR 801.109)

(Optional Format 1-2-96)